510(k) Summary
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AUG 27 2012

Company	Crospon Ltd. Galway Business Park Dangan Galway, Ireland
Official Contact:	John O'Dea PhD
Proprietary or Trade Name:	EndoFLIP® Barostat Mode
Common/Usual Name:	Gastrointestinal motility monitoring system
Classification Name:	FFX - system, gastrointestinal motility (electrical) CFR 876.1725 Class 2
Device:	EndoFLIP System and Catheter
Predicate Devices:	K991288 – G&J Electronics, Distender Series II Barostat K092850 – EndoFLIP® systems – Crospon Ltd.

Device Description:
The EndoFLIP® system and catheter are identical to the predicate K092850, except the addition of the new software which permits a programmed series of inflations of the balloon in steps of volume. This feature is equivalent to a modality offered by the predicate Barostat (K991288).

The device is not intended to perform a diagnostic test.

Indications for Use:
The EndoFLIP system is indicated for use in a clinical setting as a pressure and dimension measurement device and as an adjunct to other methods in the comprehensive evaluation of patients with symptoms consistent with esophageal sensory hypersensitivity.

Patient Population:
Patients with esophageal disorders.

Environment of Use:
Hospitals, Physician offices.

Contraindications:
The EndoFLIP® System is contraindicated where endoscopy is contraindicated.

The EndoFLIP System is contraindicated in patients with an increased risk of esophageal perforation or bleeding.

Table of Comparison of Proposed Device vs. Predicate

	Distender Series II Barostat (G&J Electronics)K991288	**EndoFLIP® Crospon (K092850)**	**EndoFLIP® Barostat Mode**
Indications for Use	The Distender Series II Dual Drive Barostat device with the Protocol Plus software is an electro-pneumatic device used for volume / pressure measurement in the alimentary tract. This device is intended to be used as an adjunct to other diagnostic methods as part of a comprehensive evaluation of patients with symptoms consistent with gastrointestinal motility disorders.	The EndoFLIP® system is an endoscopically placed device indicated for use in patients fitted with a gastric band. The device is intended to estimate the size of the stoma produced by the gastric band in a clinical setting.	The EndoFLIP system is indicated for use in a clinical setting as a pressure and dimension measurement device and as an adjunct to other methods in the comprehensive evaluation of patients with symptoms consistent with esophageal sensory hypersensitivity.
Anatomical Sites	Esophagus, stomach, small bowel, colon and rectum	Stomach	Esophagus
Environments of use	Hospitals, Physician offices	Hospitals, Physician offices	Hospitals, Physician offices
Patient Population	Patients with symptoms consistent with gastrointestinal motility disorders	Patient undergoing gastric band surgery and post-operative band adjustment	Patients with esophageal disorders
Contraindications	Not stated	The EndoFLIP® System is contraindicated where endoscopy is contraindicated.	The EndoFLIP® System is contraindicated where endoscopy is contraindicated. The EndoFLIP System is contraindicated in patients with an increased risk of esophageal perforation or bleeding.
Prescription	Prescription use	Prescription use	Prescription use
Principle of Operation	Pneumatic device that maintains an isobaric pressure or isovolumetric volume within a balloon. Records volume and pressure changes during the protocol.	The catheter is positioned in the stoma within a stomach fitted with a gastric band, which in turn permits the stoma diameter to be measured and to be set to a desired size.	The catheter is positioned in the esophagus There are up to ten isovolumetric steps which can be pre-programmed. These steps are programmed in terms of the volume to be delivered and the time to pause between each step. Alternatively the system can be programmed to allow the patient to decide when the next step commences

	Distender Series II Barostat (G&J Electronics)K991288	EndoFLIP® Crospon (K092850)	EndoFLIP® Barostat Mode
Principle of Operation	Pressure sensor in the device is connected to the balloon via a measurement line.	Pressure sensor in the catheter balloon. D_{est} electrodes are located at 16 points along the catheter inside a balloon. The balloon is placed such that its midpoint is located in a stoma within a stomach fitted with a gastric band	Pressure sensor in the catheter balloon. D_{est} electrodes are located at 16 points along the catheter inside a balloon. The balloon is placed such that its midpoint is located in the esophagus.
Data Recording	4 channels of data can be recorded on a chart recorder	Data is saved internally and can be exported to a USB mass storage device or printed to an attached USB printer	Data is saved internally and can be exported to a USB mass storage device or printed to an attached USB printer
Electrical Safety	Not stated	IEC60601-1 2nd Ed. + Am.1 + Am.2	IEC60601-1 2nd Ed. + Am.1 + Am.2
Biocompatibility	User sources balloons and tubing.	All materials have passed biocompatibility tests in accordance with ISO 10993-1	Identical to K092850
Compatibility With The Environment And Other Devices	User sources balloons and tubing.	EndoFLIP operates with custom catheters only.	EndoFLIP operates with custom catheters only.
Performance	Volume range and resolution is dependent on the cylinder size used. Range available is 25ml to 1200ml. Resolution ranges from a piston step size of 0.181ml to 0.804ml	Balloon volume is controlled and volume is displayed: Range: 0 to 50 mL Resolution: 1 mL	Balloon volume is controlled and volume is displayed: Range: 0 to 50 mL Resolution: 1 mL

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Substantial Equivalence

The EndoFLIP® system in Barostat mode is viewed as substantially equivalent to the predicate devices presented above. In summary we have found that the following key elements support a determination of substantially equivalent:

Indications –
The proposed indications for use are nearly identical to the predicate, Barostat K991288.

The EndoFLIP system is indicated for use in a clinical setting as a pressure and dimension measurement device and as an adjunct to other methods in the comprehensive evaluation of patients with symptoms consistent with esophageal sensory hypersensitivity vs. the predicate Distender Series II Dual Drive Barostat device which is used for volume/pressure measurement in the alimentary tract as an adjunct to other diagnostic methods as part of a comprehensive evaluation of patients with symptoms consistent with gastrointestinal motility disorders.

Note: EndoFLIP is a measurement system. It is not intended to perform a diagnostic test.

Environment of Use –
The proposed environments of use are identical to the predicates, EndoFLIP® K092850 and Barostat (K991288), which are for Hospitals and Physician offices.

Patient Population –
The proposed patient population is patients with esophageal disorders whereas the predicate Barostat (K991288) lists patients with symptoms consistent with gastrointestinal motility disorders, which are equivalent.

Technology / Design / Features –
The technology is identical to the predicate EndoFLIP® systems (K092850) and we have only added a new software feature which is the Barostat mode, which allows programmed volume distentions, each volume distention being identical in nature to the single volume distention permitted using the existing software.

Materials –
The materials are identical to the predicate EndoFLIP® K092850 and thus not applicable as the modification is software only.

Performance Specifications –
The proposed software modification does not change the performance specification of the EndoFLIP®, which remains identical to the predicate K092850.

Performance Testing – Bench.
No comparative bench testing was required as the change is a software change only.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Crospon, Ltd.
% Mr. Paul Dryden
President
ProMedic, Inc.
24301 Woodsage Drive
BONITA SPRINGS FL 34134

AUG 27 2012

Re: K120997
Trade/Device Name: EndoFLIP® Barostat
Regulation Number: 21 CFR§ 876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: FFX
Dated: August 20, 2012
Received: August 21, 2012

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K120997

Device Name: EndoFLIP® Barostat

Indications for Use:

The EndoFLIP system is indicated for use in a clinical setting as a pressure and dimension measurement device and as an adjunct to other methods in the comprehensive evaluation of patients with symptoms consistent with esophageal sensory hypersensitivity.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120997